K101587

ProPatch® Soft Tissue Repair Matrix Special 510(k) Submission
CryoLife, Inc.

## 510(k) Summary

SEP 16 2010

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| Submitter: | CryoLife, Inc. |
| Contact: | Bryan Brosseau<br>Regulatory Affairs Specialist |
| Address: | 1655 Roberts Blvd. NW<br>Kennesaw, GA 30144 |
| Phone: | 770-419-3355 |
| Fax: | 770-590-3783 |
| Date: | June 4, 2010 |
| Trade Name: | ProPatch® Soft Tissue Repair Matrix |
| Common Name: | Surgical Mesh |
| Classification Name: | Mesh, Surgical (21 CFR 878.3300, Product Code FTM) |
| Predicate Device: | ProPatch® Soft Tissue Repair Matrix<br>K061892 - 11/22/2006<br>CryoLife, Inc.<br>1655 Roberts Blvd. NW<br>Kennesaw, GA 30144 |

Intended Use:

ProPatch® is indicated for implantation to reinforce soft tissues where weakness exists including, but not limited to: defects of the abdominal and thoracic wall, muscle flap reinforcement, rectal and vaginal prolapse, reconstruction of the pelvic floor, hernias, suture-line reinforcement, and reconstructive procedures.

ProPatch is indicated for the reinforcement of soft tissues repaired by sutures or by suture anchors during tendon repair surgery including, but not limited to: reinforcement of rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons.

Device Description:

ProPatch Soft Tissue Repair Matrix (ProPatch) is a surgical mesh manufactured from decellularized bovine pericardium. Decellularized tissues undergo chemical microbial

and viral inactivation processes, are inspected for freedom from defects, packaged, and terminally sterilized via gamma radiation.

ProPatch is comprised of a single layer, nominally 0.6 mm thick, and is provided as a sterile and non-pyrogenic product that is fully hydrated and ready for use without the need for rinsing or rehydration prior to implantation.

Equivalence to Predicate Device:

This submission is related to changes to the ProPatch Instructions for Use and a minor manufacturing change. The indicated uses and technological characteristics are identical to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

CryoLife, Incorporated
% Mr. Bryan Brosseau
Regulatory Affairs Specialist
1655 Roberts Boulevard Northwest
Kennesaw, Georgia 30144

JUN 22 2012

Re: K101587
Trade/Device Name: ProPatch® Soft Tissue Repair Matrix
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM, OXK, OXB, OXH, OXE, OWY
Dated: August 25, 2010
Received: August 27, 2010

Dear Mr. Brosseau:

This letter corrects our substantially equivalent letter of September 16, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin L. Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

**Indications for Use**

510(k) Number (if known): K101587

Device Name: ProPatch® Soft Tissue Repair Matrix

Indications for Use:

Non-Joint Related Repair
ProPatch is indicated for implantation to reinforce soft tissues where weakness exists including, but not limited to: defects of the abdominal and thoracic wall, muscle flap reinforcement, hernias, suture-line reinforcement, and reconstructive procedures.

Joint Related Repair
ProPatch is indicated for the reinforcement of soft tissues repaired by sutures or by suture anchors during tendon repair surgery including, but not limited to: reinforcement of rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K101587